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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Z-3048/04	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/EP2005/000206	International filing date (day/month/year) 12.01.2005	Priority date (day/month/year) 15.01.2004	
International Patent Classification (IPC) or national classification and IPC A61K35/78, A61P3/04			
Applicant BRINGWELL INTERNATIONAL AB et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 07.11.2005		Date of completion of this report 15.02.2006	
Name and mailing address of the International preliminary examining authority:  European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840		Authorized Officer Mateo Rosell, A.M. Telephone No. +49 30 25901-	



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2005/000206

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the International application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-13 as originally filed

Claims, Numbers

1-16 as originally filed

Drawings, Sheets

1/10-10/10 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or Industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-16
	No: Claims	
Inventive step (IS)	Yes: Claims	1-16
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-16
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY
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Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following document:

D1: Dullooo et al., 1999.Am.J.Clin.Nutr., 70: 1040-1045.

Novelty

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1 and shows that (see abstract and page 1041, left-hand column, 3rd paragraph to right-hand column, 1st paragraph; page 1042, right-hand column, last paragraph to page 1044, right-hand column, last paragraph) the references in parentheses applying to this document) the administration of a green tea extract, AR25 in form of capsules (containing 50 mg caffeine and 90 mg epigallocatechin gallate), promotes a significant increase in fat oxidation as compared to subjects taking caffeine alone (50 mg caffeine) or placebo.

The subject-matter of claims 1 and 9 differ from this known D1 in that the formulation of the present application incorporates diterpene forskolin, caffeoylquinic acids and flavonoids to the caffeine and catechines.

The subject-matter of claims 1 and 9 is therefore new (Article 33(2) PCT).

Inventive step

The problem to be solved by the present invention may be regarded as the provision of a pharmaceutical composition to treat obesity and associated metabolic syndrome.

The solution to this problem proposed in claims 1 and 9 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

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The combination of different extracts obtained from green tea (catechins such as epigallocatechin galate (EGCG)), Coleus forskholii (diterpene forskolin), yerba mate (caffeine and caffeoylquinic acids (cGA)) and Betula alba (flavonoids) act in concert, i.e. synergistically strengthening the two main effects of the mixture, i.e. the thermogenic effect (increased metabolic rate) and the decrease of the absorption of fat (see examples 3-5).

Claims 2-8 and 10-16 are dependent on claims 1 and 9 and as such also meet the requirements of the PCT with respect to novelty and inventive step.